

Appl. No. 09/643,686
Amendment dated December 15, 2004
Reply to Office Action of June 15, 2004

Remarks

Entry of the amendment is respectfully requested since it would reduce the issues on appeal and is believed to be fully supported by the application as filed.

Upon entry of the amendment Claims 2-19, 22-23, 27 and 28 are pending in the application, with claims 27 and 28 being independent claims. Claims 24-26 have been withdrawn from consideration. Claim 27 has been amended to clearly indicate in the preamble the nature of the immunoassay set forth in the body of the claim, e.g. "sandwich". Claim 28 has been added to more clearly set forth inventive aspects of the invention.

Based on the present Amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

This Amendment is being submitted concurrently with a Notice of Appeal.

Rejections under 35 U.S.C. § 103

Claims 2-19, 22-23 and 27 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Lekkala et al. (WO 95/22754) in view of Babson et al. (U.S. Patent No. 5,885,530). Applicants respectfully traverse.

Lekkala et al. describes a device and method which relies on a different assay formula than that claimed and disclosed. Lekkala et al. does not employ labels and does not employ conditions which result in the formation of antibody-antigen-antibody complex. See page 6 starting at line 20. Lekkala et al. measures a difference in reflected light due to a resonance phenomenon. The resonance phenomenon relied upon by Lekkala et al. amplifies the so-called evanescent electric field, which is generated in the total reflection. A evanescent field, created by a light source, "sees" the reaction taking place on the reaction surface (material layer), e.g. the formation of a complex between the antibody bound on the material layer and the antigen analyt in the sample, because the reaction

correspondence to a definite change of the refraction index, due to the formed complex, on the surface of the material layer. The degree of binding can be measured from the reflected light because resonance (disappearance of light) is shifted to another value of incident angle. See page 3 starting at line 26. The measurement based on this SPR phenomenon is conducted from the direction of the bottom of the structure through a suitable prism structure. If one contrasts the figures of the instant application with those of Lekkala et al., e.g. figures 2a-2c and 4a-b, one can readily see the differences in the measurement mechanism. Lekkala et al. measures the degree of binding due to a loss in the reflected light. The instant invention measures the florescence or phosphorescence due to the bound label at an angle distinct from that of the reflect light beam. See, for example, instant Figure 1. This different assay protocol necessitates different positioning of device elements, e.g. receiver (10) relative to those of Lekkala et al.

Babson et al. patent has been reviewed. It is not seen how it remedies the deficiencies of Lekkala et al., noted above. While Babson et al. does teach an automated immunoassay analyzer, this analyzer is not based on either the Lekkala et al. SBR based assay or the sandwich assay device claimed. There is no mention of the SPR or an equivalent phenomenon nor is the Babson et al. device set up to measure light differences like those disclosed by Lekkala et al. Babson et al. employ a traditional heterogeneous immunoassay format. The Babson et al. substrate for the immobilized phase are a collection of beads and not the bottom surface of an assay well. The Babson et al. measurement mechanism and device is distinct from that used either for Lekkala et al. SPR based device or that claimed.

The propriety of the reference combination is questioned. It is not seen how or why one would combine the references. There is no apparent problem in either reference for which the other provides a solution. There is not even a similarity in assay format. Lekkala et al. teaches as an advantage the absence of labels. Babson et al. employs labels. Further, the use of labels in Lekkala et al. assay format would necessitate changes in the measuring device. There is no guidance as to how the requisite changes would be made. There is no motivation referred to in the Office Action

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which would suggest why the changes would be made, even if they were taught.

It is respectfully requested that the rejection be withdrawn since a proper prima facie case of obviousness has not been established based on the assembled references.

Conclusion

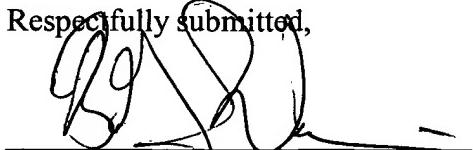
All of the stated grounds of rejections have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance.

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is hereby invited to telephone the undersigned at the number provided.

A Notice of Allowance with claims 2-19, 22-23, 27 and 28 is respectfully requested.

Date: 12/15/04

Respectfully submitted,



Thomas G. Wiseman
Registration No. 35,046
VENABLE LLP
P.O. Box 34385
Washington, D.C. 20043-9998
Telephone: (202) 344-4800
Telefax: (202) 344-8300

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